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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,317	01/14/2002	Iain F. McVey	MED 2 1221 US	7063

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EXAMINER

JASTRZAB, KRISANNE MARIE

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,317

Applicant(s)

MCVEY ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended to limit claim 18 to injection of the formed antimicrobial dispersion (which is claimed as being formed with the second carrier gas stream) into the second carrier gas stream, however, the original disclosure clearly creates the dispersion with the second gas stream but injects that dispersion into the first gas stream. Clarification and correction are required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 12 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1, 12, 18, these claims are found to be vague and indefinite because the language within the claim regarding the connection between the vaporizer and the two carrier gas flows is written in a confusing manner. It appears that one could read those passages with two different interpretations, one where the second gas flow is used to create an antimicrobial dispersion in the vaporizer and the dispersion is then supplied to the duct carrying the first carrier stream, or that a first duct contains the first stream flow and another duct is provided for supplying the second carrier gas flow. Based on the specification and the drawings, the Examiner holds the first instance as the proper interpretation and has examined the claims as such. It is suggested that the language of the claims (particularly 1 and 12) be changed to delete the citation of "for supplying the second carrier gas flow and vapor", and replace that with language defining the mixture or dispersion of the two.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 12, 16-18, 20-21 and 30-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cummings et al., U.S. patent No. 4,909,999.

Cummings et al., teach a flow-through vapor phase sterilization system and its use, which employs hydrogen peroxide as the applied antimicrobial agent. Duct means are provided for a first carrier gas flow there through to an enclosure to be sterilized. A

second carrier gas flow is established which is directed to a vaporizer block means having metal components and intersecting bores which turn 180° in the flow path and which expands in cross section between the inlet and outlet. The second carrier gas flow picks up antimicrobial that is instantaneously, or flash, vaporized and the dispersion of the two is then supplied to the duct carrying the first carrier gas stream at a mixing point prior to injection into the enclosure to be treated. Fans may be employed in the enclosure to ensure turbulent treatment of the interior. Flow metering means control the injection of the liquid for vaporization and filtration of the carrier air to remove contaminants. See column 4, lines 40-45 and 55-68, column 5, lines 1-16 and lines 50-57, column 6, lines 1-20, column 7, lines 6-35 and column 8, lines 45-46, and Figs. 1, 5 and 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 8-11, 19, 22-24 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al., as applied to claims 1-4, 6-7, 12, 16-18, 20-21 and 30-33 above, and further in view of Childers et al., 5,876,664.

Childers et al., teach a closed loop decontamination system employing hydrogen peroxide vapor, which is vaporized in a metal block flash vaporizer. The vaporizer has an internal passage forming a torturous path having at least two 90° turns with walls in between, which act to optimize vapor formation by minimizing vapor degradation during flow through the vaporizer. Childers et al., also teach employing carrier gas flow rates exceeding 20 scfm (which exceed 20 cubic meters per minute as well). The carrier gas of Childers et al., is also filtered both when removed from the treated area and in a recycle loop to eliminate potential bacterial contamination of the system by the carrier gas, and of the atmosphere by any off-gassed carrier gas. The carrier air is heated and dried to maintain it's ability to pick up the vaporized sterilant. See column 2, lines 12-20

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and lines 60-68, column 3, lines 1-20, and lines 58-64, column 4, lines 47-55 and column 7.

With respect to claim 5, it would have been well within the purview of one of ordinary skill in the art to configure the vaporizer of Cummings et al., to have at least two 90° turns with walls in between, because it would act to optimize vapor formation by minimizing vapor degradation during flow through the vaporizer.

With respect to claim 19, it would have been obvious to one of ordinary skill in the art to employ flow rates in Cummings et al., as those taught in Childers et al., because such rates are taught to optimize vapor delivery to minimize condensation within the enclosure.

Claims 8-11, 13-15, 22-24 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al., as applied to claims 1-4, 6-7, 12, 16-18, 20-21 and 30-33, and further in view of Edwards U.S. patent No. 6,077,480.

Edwards teaches a sterilization system for large enclosures employing a plurality of flash vaporizers in conjunction with supply lines to optimize delivery of sterilant to large enclosures. Edwards further teaches the effectiveness of providing heating and dehumidifying means for the carrier air to ensure vaporization of the sterilant is not compromised by the presence of too much water vapor in the carrier air. Finally, Edwards teaches means to control the system based on the feedback from a plurality of monitoring means for system parameters to maintain sterilization conditions until sterilization is achieved. See column 1, lines 5-11, column 2, lines 40-68, column 3, lines 48-68, and column 4, lines 8-21.

It would have been obvious to one of ordinary skill in the art to employ a plurality of vaporizers in Cummings et al., as taught in Edwards because it would optimize efficient delivery of the vapor to large enclosures as treated in Cummings. It would also have been obvious to employ heating and drying means as well as the control means of Edwards because they would ensure optimized formation of the sterilant vapor and effective control of sterilization parameters to meet the sterilization requirements.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al., together with Edwards as applied to claims 8-11, 13-15, 22-24 and 27-29 above, and further in view of Rainwala U.S. patent No. 6,645,429.

Rainwala teaches a sterilization system for delivering a vaporized sterilant to a large enclosure to be treated wherein the existing HVAC duct system is employed for that delivery. See column 5, lines 1-22.

It would have been obvious to one of ordinary skill in the art to employ an existing HVAC duct system for the delivery of the sterilant of the combination above for large enclosures because it would have simplified the system requirements while maintaining delivery effectiveness.

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. The amendment after final, filed 10/24/2005 has been entered, and this action is based upon the claims as presented in that amendment.

Response to Arguments

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

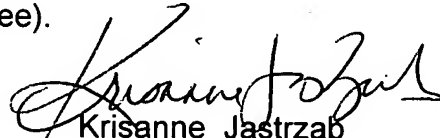
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krisanne Jastrab
Primary Examiner
Art Unit 1744

November 22, 2005